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21 **UNITED STATES DISTRICT COURT**  
22 **NORTHERN DISTRICT OF CALIFORNIA**  
23 **OAKLAND DIVISION**

24 ARINDAM BANERJEE Individually and on  
25 Behalf of All Others Similarly Situated,

26 Plaintiffs,

27 v.

28 AVINGER, INC., JEFFREY M. SOINSKI,  
MATTHEW B. FERGUSON, DONALD A.  
LUCAS, JOHN B. SIMPSON, JAMES B.  
MCELWEE, JAMES G. CULLEN, THOMAS J.  
FOGARTY, CANACCORD GENUITY, INC.,  
COWEN AND COMPANY LLC,  
OPPENHEIMER & CO., BTIG, LLC, and  
STEPHENS INC.,

Defendants.

Case No. 17-cv-03400-CW

**CLASS ACTION**

**CONSOLIDATED CLASS ACTION  
COMPLAINT FOR VIOLATIONS OF  
THE FEDERAL SECURITIES LAWS**

**DEMAND FOR JURY TRIAL**

1 Plaintiffs Arindam Banerjee and Jogesh Harjai, Court-appointed Lead Plaintiffs, together with  
 2 the Additional Plaintiffs identified herein (collectively, with Lead Plaintiffs, “Plaintiffs”), by and  
 3 through their attorneys, allege the following based upon information and belief, except as to those  
 4 allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs’ information  
 5 and belief is based upon, among other things, Plaintiffs’ counsel’s investigation, which includes,  
 6 among other things, review and analysis of (1) regulatory filings made by Avinger, Inc. (“Avinger” or  
 7 the “Company”) with the U.S. Securities and Exchange Commission (“SEC”); (2) analyst and media  
 8 reports concerning Avinger; (3) copies of press releases issued by, transcripts of conference calls  
 9 hosted by, Avinger; and (4) information obtained from interviews of former employees of the  
 10 Company.

### 11 **SUMMARY OF THE ACTION**

12 1. This is a class action on behalf of all persons and entities that purchased or otherwise  
 13 acquired shares of Avinger common stock pursuant and/or traceable to the Company’s materially  
 14 false, misleading, and incomplete Registration Statement and accompanying Prospectus incorporated  
 15 therein (collectively, the “Offering Documents” or “IPO Registration Statement”) issued in connection  
 16 with Avinger’s January 30, 2015 initial public offering (“IPO” or “Offering”). Plaintiffs pursue  
 17 remedies pursuant to the Securities Act of 1933 (“Securities Act”).

18 2. Avinger is purportedly a commercial-stage medical device company that designs,  
 19 manufactures, and sells image-guided, catheter-based systems that are used by physicians to treat  
 20 patients with peripheral artery disease (“PAD”). The Offering Documents stated that Avinger’s  
 21 mission was to improve the treatment of vascular disease through the introduction of products based  
 22 on its “lumivascular platform,” which the Offering Documents described as “the only technology that  
 23 offers real-time visualization of the inside of the artery during PAD treatment.” The Offering  
 24 Documents further stated that the Company believed that the approach offered by its technology “will  
 25 significantly improve patient outcomes by providing physicians with a clearer picture of the artery  
 26 using radiation-free image guidance during treatment, enabling them to better differentiate between  
 27 [arterial] plaque and healthy arterial structures,” and to thereby avoid, or significantly reduce, the  
 28 kinds of arterial damage or other complications (such as restenosis) associated with other forms of

1 PAD treatment. The Offering Documents noted that Avinger's "current suite" of commercially  
 2 available lumivascular products included its "Lightbox imaging console" and its "Ocelot family of  
 3 catheters," which were designed to allow physicians to penetrate (cut through) a total blockage in an  
 4 artery (known as a chronic total occlusion or "CTO").<sup>1</sup>

5 3. However, as part of Avinger's stated mission to "dramatically improve" the treatment  
 6 of vascular disease through the introduction of products based on its "lumivascular platform," the  
 7 Offering Documents placed particular stress on the critical importance of Avinger's new Pantheris  
 8 device, which was described as an "image-guided atherectomy"<sup>2</sup> device, designed to allow physicians  
 9 to remove arterial plaque in PAD patients with precision." As the Offering Documents further stated,  
 10 Pantheris was in the middle of a clinical trial in the U.S. (the "VISION" trial), which was designed to  
 11 support an application to the U.S. Food and Drug Administration ("FDA") for 510(k) clearance (to  
 12 permit commercial sales of the device) in the second half of 2015. As of the date of the IPO, 116  
 13 patients at 19 separate sites (out of a total planned enrollment of roughly 133 patients) had already  
 14 been enrolled in the VISION trial. Avinger touted Pantheris in the prospectus, describing it as the  
 15 "first atherectomy catheter to incorporate real time OCT [optical coherence tomography] intravascular  
 16 imaging," and stating that "[w]e believe that Pantheris will significantly enhance our market  
 17 opportunity within PAD and can expand the overall addressable market for PAD endovascular  
 18 procedures."

19 4. In the IPO, Avinger sold five million shares at a public offering price of \$13.00 per  
 20 share. The Company received net proceeds of approximately \$56.9 million from the IPO.

21 5. However, unbeknownst to investors, as of the date of the IPO, Avinger's all-important  
 22 Pantheris product suffered from significant product defect and reliability issues. As a result, the

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23  
 24 <sup>1</sup> The Offering Documents also noted that Avinger's *non*-image based "Wildcat" and  
 25 "Kittycat2" catheter products were still commercially available, but that its sales of those products  
 26 "have declined and continue to decline as we focus on the promotion of our lumivascular platform  
 27 products." Indeed, the Offering Documents further stated that Avinger had significantly reduced the  
 number of its employees in the last 18 months, from 168 to 115, "to better align resource utilization  
 with our corporate strategy as we transitioned our focus from non-imaging products to lumivascular  
 platform products, including Pantheris."

28 <sup>2</sup> An "atherectomy" is a procedure that utilizes a catheter with a sharp blade at the end to remove  
 plaque from a blood vessel. The catheter is inserted into the artery through a small puncture in the  
 artery.

1 Offering Documents were materially false and misleading and omitted to state: (1) that the Company's  
2 Pantheris product had substantial product defect and/or design problems and related reliability issues;  
3 (2) that the Company lacked an adequate basis for giving Pantheris "passing" grades in its verification  
4 and validation product testing; (3) that the problems and related reliability issues with Pantheris would  
5 likely have a negative impact on Avinger's net sales, revenues and income, and jeopardize Avinger's  
6 ability to successfully launch Pantheris on a commercial basis; and (4) that as a result of the foregoing,  
7 the statements in the Offering Documents regarding Avinger's business, operations, and prospects  
8 were materially false, misleading and/or incomplete, and/or lacked a reasonable basis.

9         6. For example, as various former Avinger employees identified herein as Confidential  
10 Witnesses ("CWs"), confirmed, prior to and as of the IPO, Pantheris was suffering from significant  
11 problems involving its fiber-optic cables, and resulting imaging problems. In particular, as Avinger  
12 engineering personnel had concluded, Avinger's testing of the Pantheris device failed to adequately  
13 simulate real-world use, notably in connection with tortuosity (involving the ability of the product to  
14 make turns as it navigates through the vasculature), and the Company's engineers therefore repeatedly  
15 asked Avinger's Chief Technology Officer, including prior to the IPO, that the Company to take steps  
16 to significantly improve the quality, reliability, and durability of the fiber optic cable used in the  
17 Pantheris. However, these requests were repeatedly rebuffed.

18         7. The significant and undisclosed problems with Avinger's Pantheris product, which also  
19 included problems related to the tiny balloons that were deployed from the Pantheris device in  
20 connection with its use in the vasculature, would ultimately come back to haunt the Company – and  
21 torpedo the value of class members' investments in its shares. For example, on July 12, 2016, the  
22 Company announced disappointing preliminary second quarter 2016 results, which it attributed largely  
23 to "lower than expected" utilization of Pantheris in the second quarter. Avinger also reported that  
24 customer complaints had forced it to try to implement corrective changes to the Pantheris, including  
25 with respect to improving its fiber optic imaging cables and robustness. Analysts reacted negatively to  
26 these disclosures, with one describing management's commentary about the product quality problems  
27 as "alarming." On July 13, 2016 alone, Avinger's stock price fell \$4.54 (or 39.7%), from \$11.43 to  
28 only \$6.89 per share on unusually heavy trading volume. As Pantheris continued to be plagued by

1 product problems and related product returns, customer complaints and dismal sales – and with  
 2 Avinger also later admitting that it needed to significantly toughen its product testing and validation  
 3 protocols if it wanted to avoid a similarly disastrous commercial launch for future “improved”  
 4 generations of Pantheris product –Avinger’s stock price has only continued to decline. Indeed, as  
 5 recently as November 21, 2017 (the date of this filing), the price of Avinger’s common stock closed at  
 6 only \$0.23 per share – reflecting a staggering decline of \$12.77, *or a more than a 98% decline*, from  
 7 its IPO price of \$13.00 per share. Plaintiffs now bring this action, on behalf of themselves and the  
 8 Class that they seek to represent, to recover damages under the strict liability provisions of the  
 9 Securities Act for the staggering losses that they and the Class have suffered in connection their  
 10 purchases of Avinger shares.

#### 11 **JURISDICTION AND VENUE**

12 8. The claims asserted herein arise under and pursuant to §§11 and 15 of the Securities  
 13 Act (15 U.S.C. §§77k and 77o). This Court has jurisdiction over the subject matter of this action  
 14 pursuant to §22 of the Securities Act, 15 U.S.C. §77v.

15 9. Venue is also proper in this District under §22 of the Securities Act, 15 U.S.C. §77v(a),  
 16 which provides that any suit under the Act may be brought “in the district wherein the defendant is  
 17 found or is an inhabitant or transacts business[.]” Many of the violations of law complained of herein  
 18 occurred in this District, including the dissemination of the materially false and misleading statements  
 19 complained of herein. In addition, Avinger’s principal executive offices are located in this District.  
 20 Each of the other Defendants also has sufficient contacts with this District, or otherwise purposefully  
 21 availed himself or itself of benefits of this District, so as to render the exercise of jurisdiction over  
 22 each by this District consistent with traditional notions of fair play and substantial justice.

#### 23 **PARTIES**

24 10. Lead Plaintiffs Arindam Banerjee and Jogesh Harjai purchased shares of Avinger  
 25 common stock pursuant and/or traceable to the Offering Documents issued in connection with the IPO  
 26 and have been damaged thereby.

1           11.     Plaintiffs Lindsay Grotewiel and Todd Vogel (the “Additional Plaintiffs”) purchased  
2 shares of Avinger common stock pursuant and/or traceable to the Offering Documents issued in  
3 connection with the IPO and have been damaged thereby.

4           12.     Defendant Avinger is incorporated in Delaware and its principal executive offices are  
5 located at 400 Chesapeake Drive Redwood City, California 94063. Its common stock trades on the  
6 NASDAQ Stock Market (the “NASDAQ”) under the symbol “AVGR.”

7           13.     Defendant Jeffrey M. Soinski (“Soinski”) was, at all relevant times, the Chief Executive  
8 Officer (“CEO”) and a Director of Avinger and signed or authorized the signing of the Company’s  
9 IPO Registration Statement filed with the SEC.

10          14.     Defendant Matthew B. Ferguson (“Ferguson”) was, at all relevant times, the Chief  
11 Financial Officer (“CFO”) and Chief Business Officer (“CBO”) of Avinger and signed or authorized  
12 the signing of the Company’s IPO Registration Statement filed with the SEC.

13          15.     Defendant John B. Simpson (“Simpson”) was, at all relevant times, the Executive  
14 Chairman of the Board of Directors of Avinger and signed or authorized the signing of the Company’s  
15 IPO Registration Statement filed with the SEC.

16          16.     Defendant Donald A. Lucas (“Lucas”), at all relevant times, was a Director of Avinger  
17 and signed or authorized the signing of the Company’s IPO Registration Statement filed with the SEC.

18          17.     Defendant James B. McElwee (“McElwee”), at all relevant times, was a Director of  
19 Avinger and signed or authorized the signing of the Company’s IPO Registration Statement filed with  
20 the SEC.

21          18.     Defendant James G. Cullen (“Cullen”) was, at all relevant times, a Director of Avinger  
22 and signed or authorized the signing of the Company’s IPO Registration Statement filed with the SEC.

23          19.     Defendant Thomas J. Fogarty (“Fogarty”) was, at all relevant times, a Director of  
24 Avinger and signed or authorized the signing of the Company’s IPO Registration Statement filed with  
25 the SEC.

26          20.     Defendants Soinski, Ferguson, Lucas, Simpson, McElwee, Cullen, and Fogarty are  
27 collectively referred to hereinafter as the “Individual Defendants.”  
28

21. Defendant Canaccord Genuity Inc. (“Canaccord”) served as an underwriter for the IPO. In the IPO, Canaccord agreed to purchase 1,750,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

22. Defendant Cowen and Company LLC (“Cowen”) served as an underwriter for the IPO. In the IPO, Cowen agreed to purchase 1,750,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

23. Defendant Oppenheimer & Co. (“Oppenheimer”) served as an underwriter for the IPO. In the IPO, Oppenheimer agreed to purchase 500,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

24. Defendant BTIG, LLC (“BTIG”) served as an underwriter for the IPO. In the IPO, BTIG agreed to purchase 500,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

25. Defendant Stephens Inc. (“Stephens”) served as an underwriter for the IPO. In the IPO, Stephens agreed to purchase 500,000 shares of Avinger common stock, exclusive of its option to purchase additional shares.

26. Defendants Canaccord, Cowen, Oppenheimer, BTIG, and Stephens are collectively referred to hereinafter as the “Underwriter Defendants.” The Underwriter Defendants received lucrative fees and commissions, totaling in excess of \$4.5 million, for their role in the IPO.

### **SUBSTANTIVE ALLEGATIONS**

#### **A. The Company’s False and/or Misleading Offering Documents**

27. On January 29, 2015, Avinger filed an amendment to the Form S-1 registration statement originally filed on December 30, 2014. The amendment, which included the text of the IPO Prospectus dated January 29, 2015, forms part of the IPO Registration Statement.

28. In the Prospectus, the Company emphasized the critical importance of its Pantheris product, and how its unique real-time imaging capabilities provided the basis for a dramatic improvement in vascular disease by allowing physicians to remove only harmful arterial plaque while avoiding healthy arterial tissue. For example, the Prospectus stated:



***We are . . . developing Pantheris, our image-guided atherectomy device, designed to allow physicians to remove arterial plaque in PAD patients with precision.***

Pantheris is currently undergoing a U.S. clinical trial intended to support a 510(k) submission in the second half of 2015 to the U.S. Food and Drug Administration, or FDA. We believe that Pantheris, if cleared by FDA, will significantly enhance our market opportunity within PAD and can expand the overall addressable market for PAD endovascular procedures.

Current treatments for PAD, including bypass surgery, can be costly and may result in complications, high levels of post-surgery pain and lengthy hospital stays and recovery times. Minimally invasive, or endovascular, treatments include stents, angioplasty, and atherectomy devices, which are catheter-based products for the removal of plaque. These treatments also have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease, also known as restenosis. We believe one of the main contributing factors to high restenosis rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Specifically, these treatments often disrupt the membrane between the outermost layers of the artery, which we refer to as the black line.

***Our lumivascular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment. We believe this approach will significantly improve patient outcomes by providing physicians with a clearer picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between plaque and healthy arterial structures. Our lumivascular platform is designed to improve patient safety by enabling physicians to direct treatment towards the plaque, while avoiding healthy portions of the artery.***

During the third quarter of 2014, we began enrolling, and we are continuing to enroll, patients in VISION, a clinical trial designed to support a filing with FDA for our Pantheris atherectomy device. VISION is designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging. Data collection from the VISION trial is ongoing and data monitoring and auditing of the acute procedural data and 30-day follow-up data is currently underway. As of January 12, 2015, preliminary acute procedural data were available for 116 patients, and 30-day follow-up data were available for 35 of these patients, and results reviewed by an independent core lab are available for 113 lesions.

\* \* \*

### **Our Solution**

We believe the combination of enhanced visualization and the ability to precisely target the diseased portion of an artery will allow physicians to access difficult to treat areas and significantly improve the safety and efficacy of endovascular procedures for patients. We believe that our lumivascular platform provides the following benefits to physicians, hospitals and patients:

- ***Improved efficacy through reduced risk of restenosis.*** Our lumivascular platform is designed to provide physicians with a clear picture from inside the artery during treatment. This visualization helps physicians to avoid disrupting the black line during an intervention, which we believe reduces the risk of restenosis.



1           •       ***Safety of endovascular procedures.*** Serious adverse events such as  
2 perforations and dissections may be reduced during endovascular procedures  
using our lumivascular platform.

3           •       ***Expanded patient population eligible for endovascular treatment of***  
4 ***PAD.*** Our lumivascular platform is designed to allow physicians to treat  
complex PAD cases due to our increased CTO crossing success rates. Due to  
5 improved safety of our lumivascular platform products, we believe  
physicians will be more likely to use our products to treat patients who would  
6 otherwise be medically managed.

7                               \* \* \*

8           Our pioneering lumivascular platform combines best-in-class interventional devices  
with optical coherence tomography, or OCT, a high resolution, light-based,  
9 radiation-free intravascular imaging technology. ***Our lumivascular platform***  
***currently provides physicians with real-time OCT images from the inside of an***  
10 ***artery during CTO crossing, and we believe Pantheris will be the first product to***  
***offer intravascular visualization during atherectomy.***

11                               \* \* \*

12           ***Improved efficacy through reduced risk of restenosis.*** Clinical evidence supports  
the proposition that more desirable outcomes in treating PAD are achieved by  
13 minimizing black line disruption, thereby reducing the risk of restenosis. Our  
lumivascular platform is designed to provide physicians with a clear picture from  
14 inside the artery during treatment. This visualization helps physicians to avoid  
disrupting the black line during an intervention, which we believe reduces the risk of  
15 restenosis. In addition, the directional nature of our catheters is designed to enable  
physicians to accurately target the diseased area, resulting in less damage to arterial  
16 structures and allowing for the precise removal of plaque.

17 [Emphasis added and in original.]

18           29.       On January 30, 2015, the Company filed the Prospectus with the SEC, which was  
19 incorporated by reference into the Registration Statement that was declared effective on January 29,  
20 2015. The Prospectus reaffirmed the statements identified above.

21 **B.       Reasons Why the Offering Documents Were False and Misleading**

22           30.       The IPO Registration Statement contained untrue statements of material facts or  
23 omitted to state other facts necessary to make the statements made not misleading and were not  
24 prepared in accordance with the rules and regulations governing their preparation. Under applicable  
25 SEC rules and regulations, including Item 303 of SEC Regulation S-K, the IPO Registration Statement  
26 was required to disclose known trends, events, or uncertainties that were having, and were reasonably  
27 likely to have, an unfavorable impact on the Company's net sales or revenue or income from  
28 continuing operations.

1           31.     The IPO Registration Statement was materially inaccurate, incomplete and misleading,  
2 and/or omitted to include material information required to be stated therein, because it failed to  
3 disclose: (1) that the Company's Pantheris product had substantial product defect and/or design  
4 problems and related reliability issues; (2) that the Company lacked an adequate basis for giving  
5 Pantheris "passing" grades in its verification and validation product testing; (3) that the problems and  
6 related reliability issues with Pantheris would likely have a negative impact on Avinger's net sales,  
7 revenues and income, and jeopardize Avinger's ability to successfully launch Pantheris on a  
8 commercial basis; and (4) that, as a result of the foregoing, Defendants' statements in the IPO  
9 Registration Statement regarding Avinger's products, business, operations, and prospects, were  
10 materially false, misleading, incomplete, and/or lacked a reasonable basis.

11           32.     Information provided to Plaintiffs by various CWs confirm the materially false,  
12 incomplete, and/or misleading nature of the statements contained in the Offering Documents. For  
13 example, the Offering Documents failed to disclose at the time of the IPO that the product on which  
14 Avinger's future success depended, Pantheris, was plagued by significant fiber optic cable defects and  
15 resulting imaging problems – problems that were so severe that, both before the IPO (as well as after),  
16 the Company's engineers repeatedly asked Avinger's Chief Technology Officer to take steps to  
17 improve the quality of the fiber optic cable's being used in the product, only to have their requests  
18 repeatedly rebuffed.

19           33.     According to CW1, who (after a previous stint at Avinger) worked as an R&D Engineer  
20 at the Company's Redwood, California headquarters from late 2014 until April 2017 (where CW1  
21 reported to Director of R&D Rick Newhauser and interacted daily with Chief Technology Officer  
22 ("CTO") Himanshu Patel ("Patel")), CW1 worked primarily on the Pantheris device. In this role,  
23 CW1 was responsible for the mechanical design and testing of certain components of the Pantheris  
24 device – primarily the braided driveshaft and torqueshaft components – and was also heavily involved  
25 in verification and validation ("V&V") testing, using both benchtop and animal-model testing  
26 processes. CW1 was involved in designing the V&V testing specifications, including drafting test  
27 protocols, running the tests themselves, and training technicians to perform the tests. The V&V  
28 process tested for different measurable outcomes – including the reliability and/or durability of the

1 Pantheris device – to ultimately ensure that the device’s design met all specifications and was ready to  
2 be launched commercially.

3 34. As CW1 described, Avinger’s benchtop testing on the design of the Pantheris device  
4 was “verified” by running a series of tests on the device as it rested on a benchtop, which would then  
5 be followed by a “validation” process based on animal-model testing which was purportedly meant to  
6 evaluate performance under more “real-world” conditions. For the validation process, Avinger used a  
7 pig’s aorta as a proxy to simulate the environment in which the product would be used in a human.  
8 Validation testing sought to confirm the testing results from the verification process.

9 35. V&V testing outcomes fell into one of three categories: (1) pass; (2) fail; or (3) pass  
10 with justification. The “pass with justification” category was one where the device had actually failed  
11 the V&V test, but was issued a passing grade due to a purportedly allowable justification. As CW1  
12 stated, the “pass with justification” category raised issues in terms of whether a purported justification  
13 was truly acceptable, or was simply being used as a method for Avinger to conceal and/or ignore  
14 problems to cut costs and/or keep the product’s deployment moving forward on schedule.

15 36. As CW1 stated, the V&V testing specifications for Pantheris were unrealistic in that  
16 they did not adequately simulate what the use of the device would be in the field. Specifically, CW1  
17 stated that the testing of the device was not as rigorous as CW1 and other engineers had determined to  
18 be necessary. One recurring area that CW1 and his colleagues strongly believed needed to be  
19 improved was in the area of testing the Pantheris’ tortuosity performance. As CW1 explained, the  
20 Pantheris device was intended to be able to maneuver through multiple twists and turns within the  
21 human body’s vasculature as it made its way to the problem area that required the atherectomy.  
22 However, Avinger’s V&V testing specifications only allowed for at most one turn, and sometimes no  
23 turns at all, is assessing whether the device handled properly. This lack of tortuosity in the test  
24 environment significantly increased the likelihood that a device would nominally be able to pass test  
25 specifications – which CW1 stated were too easy – even though it would be unable to satisfactorily  
26 perform in real-world conditions. In particular, as CW1 stated, in the real world maneuvering a  
27 Pantheris through the twists and turns of the vascular was a primary factor that could, and did, damage  
28 the fiber optic cable within the device, which in turn would compromise the device’s image quality.

1 And as CW1 confirmed, one of the most significant risks associated with image quality deterioration  
2 was the risk that a physician, who could not properly view the artery and related plaque blockage or  
3 build-up, would remove or damage healthy tissue portions of a patient's artery, instead of (or in  
4 addition to) arterial plaque.

5 37. Avinger's V&V testing for the Pantheris device's reliability and durability involved  
6 running the device for a certain amount of time in order to measure the device's performance. As  
7 CW1 stated, image failure in the reliability and durability segment of Avinger's V&V testing was "one  
8 of the biggest issues that we had and many of the image failures related to ongoing problems with the  
9 Pantheris' fiber optic cables. *As CW1 put it, "the level of robustness wasn't there, even pre-IPO."*

10 38. However, rather than appropriately confront these problems directly, CW1 stated that  
11 the response that Avinger adopted in response to these failures – as dictated by CTO Patel – was to  
12 "dial back the [testing] requirements," and to instead rely on "justification[s] from clinical data [from  
13 the VISION trial]." In other words, the concept was for Avinger to identify product failures from the  
14 VISION trial and then extrapolate from those observed failures to estimate how long the device could  
15 run in a given configuration. As a result, Avinger glossed over and discounted Pantheris' failures on  
16 the reliability and durability tests that the Company's engineers actually ran by instead giving the  
17 device "pass with justification" grades – even though Avinger's reliance on "clinical data" from the  
18 VISION trial for this purpose was inappropriate. In particular, the VISION trial was *not* designed to  
19 measure the Pantheris device's reliability or durability, but was instead only to test its efficacy in  
20 treating PAD on a primary patient pool of 133 patients spread out over 19 locations. Accordingly, as  
21 CW1 stated, relying on such clinical data was "a hokie justification" for converting Avinger's "fail"  
22 grades, based on its own testing, into "pass with justification" grades. CW1 stated that CTO Patel was  
23 primarily responsible for approving and directing all test specifications for Pantheris, and for allowing  
24 relevant V&V test results to be re-classified from "fail" to "pass with justification."

25 39. CW1 also described how Avinger's Senior Vice President of Operations and Quality  
26 Assurance, Bunty Banerjee, *"would butt heads constantly"* with CTO Patel with regard to these  
27 quality issues. As CW1 recalled, Banerjee regularly sought higher quality standards and results; by  
28 contrast, CTO Patel's priority was to "prove a concept, stick with that design, not worry about

1 improving anything, and then push that [product] out the door.” CW1 was aware of the ongoing  
2 dynamic between CTO Patel and Banerjee from regular meetings that CW1 attended during CW1’s  
3 tenure that were held between members of Avinger’s R&D and Quality departments to discuss quality  
4 and performance issues. In sum, CW1 stated that throughout his tenure, Avinger’s product and quality  
5 control engineers made repeated requests to Avinger’s senior management – including CTO Patel – to  
6 improve the Pantheris’ fiber-optic cable durability, both during the R&D phase and continuing even  
7 after the product was approved and commercially launched. However, Avinger’s senior management  
8 regularly rebuffed these requests. As a result, it was only after the IPO and Pantheris’ commercial  
9 launch when, in the face of increasing levels of complaints by physicians who had begun using the  
10 product in “real-world” conditions outside of the limitations of a 133 patient study, that CTO Patel and  
11 other senior Avinger management began to focus on trying to remedy the device’s fiber optic  
12 cable/imaging problems. CW1 was also emphatic that, based on his review of so-called “Wufoo”  
13 reports that were prepared in connection with post-commercialization Pantheris product returns by  
14 physicians/customers, the most common failure mode category identified in the reports related to  
15 imaging issues – and that these imaging issues largely arose from damage sustained to the fiber optic  
16 cable.

17 40. Similarly, CW2 also confirmed that problems with the Pantheris’ fiber optic cables  
18 were widely known within the Company’s headquarters prior to the IPO. CW2 worked at Avinger  
19 from the fall of 2011 to August 2016, serving initially as a Product Manager and then as Director of  
20 Commercial Operations beginning in October 2014. CW2 reported to VP of Marketing and Business  
21 Operations Phil Preuss, who reported to CFO and Chief Business Officer Ferguson.

22 41. By virtue of CW2’s role, which included efforts to assess and forecast product return  
23 rates, CW2 was concerned with the downstream impacts of the imaging problems with Pantheris.  
24 CW2 also assisted to a lesser extent with devising product training for customers to try to reduce the  
25 risk of breakage as a result of misuse. CW2 also worked on evaluating and revising sales contract  
26 terms, specifically in connection with the product warranty coverage and the recourse that customers  
27 had as a result of ongoing imaging problems. CW2 was also involved in efforts to forecast return  
28 rates, based on his review of prior product returns and customer complaint rates. Based on CW2’s

1 work, CW2 believed that roughly one-third of all returns and complaints related to imaging problems  
 2 arising from fiber optic cable quality issues. CW2 also stated that another significant issue that gave  
 3 rise to complaints and returns was the failure of the device's balloons to inflate properly (a  
 4 malfunction that prevented the device from being able to cut out arterial plaque).<sup>3</sup>

5 42. CW2 also confirmed that the R&D testing for the Pantheris was flawed and failed to  
 6 adequately account for "real world" conditions. As CW2 explained, Avinger's testing utilized a  
 7 bovine animal model, but the consistency of the animal tissue used was materially different from that  
 8 of human arteries. In particular, the animal tissue that Avinger used for modeling had a smooth  
 9 consistency which made it relatively easy to cut through; by contrast, human arteries have a much  
 10 rougher consistency which makes them much more difficult to operate in. For example, calcium  
 11 deposits, thrombin levels (which cause blood coagulation and potentially blood clots), and other  
 12 variables created to a rougher "mixed environment" in real world procedures in humans compared to  
 13 Avinger's animal model. In turn, the rougher and more mixed consistencies found in the human  
 14 vasculature cause variable shearing and feedback forces (and ultimately resistance) on the Pantheris'  
 15 cutting and fiber optic cables. The combination of the resulting "mixed variable load on the [   
 16 Pantheris device]" and the fact that the device "was spinning at a relatively high rate of speed, and  
 17 generating a tremendous amount of torque" also "caus[ed] a lot of the failures" when Pantheris was  
 18 used in real-world conditions. As such, as CW2 stated, the device required a much more robust design  
 19 to handle that variable load – which presented a fundamental engineering challenge for Avinger given  
 20 that the device was so small, with only "millimeters of space" to work with.

21 43. CW2 was also involved in assessing the extent of the medical community's willingness  
 22 to adopt Pantheris given the device's ongoing cable, imaging, navigation, cutting, and balloon  
 23 problems and related reliability and durability issues. CW2's review indicated that on the one hand,  
 24 physicians appeared to be excited about the Pantheris' new imaging functionality, but on the other  
 25 hand, there was growing frustration because it was this very functionality that was compromised due  
 26

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27 <sup>3</sup> As the Prospectus noted, during an atherectomy procedure with the Pantheris, the balloon  
 28 beneath the cutting device on the Pantheris is meant to be inflated to move the catheter closer to the  
 plaque, so that the physician can stabilize the device and adjust the cut depth into the plaque as  
 necessary.



1 to ongoing quality issues. ***Determining whether and to what extent physicians were willing to put up***  
2 ***with the hassle of dealing with defective devices was clearly a concern at Avinger***; as CW2 stated, “it  
3 was definitely something we were trying to figure out and accurately predict.”

4 44. CW2 also confirmed that the Pantheris’ defective cable and image quality problems did  
5 not merely raise concerns about irritating physicians, but also raised the issue of imaging problems,  
6 causing a physician to remove a patient’s healthy artery tissue as opposed to, or along with, the  
7 intended plague. Moreover, as CW2 also noted, because Pantheris was touted as the first device to  
8 provide intravascular visualization during an atherectomy, a defective Pantheris device could be  
9 viewed as simply reverting in functionality to the existing standard of care or status quo – that is,  
10 performing atherectomies without viewing or imaging capabilities. Such considerations also factored  
11 into Avinger’s concerns about customers ultimately invoking their product warranties and related costs  
12 and returning products, as well as lackluster sales.

13 45. Similarly, CW3, who worked as an engineer at Avinger’s Redwood City headquarters  
14 from the summer of 2011 to the spring of 2017, including as a Senior Manufacturing Engineer  
15 (through mid-summer 2014), Principal Manufacturing Engineer (through mid-2016), and Principal  
16 Quality Engineer (through the spring of 2017), further confirmed that Pantheris continually suffered  
17 from ongoing manufacturing and quality problems relating to imaging issues due primarily to broken  
18 or damaged optical fiber. As Principal Manufacturing Engineer, CW3 was chiefly responsible for the  
19 Pantheris device, which included working with the R&D department during the development phase of  
20 Pantheris production and then overseeing its commercial production beginning in 2015.

21 46. As CW3 recalled, CW3 first became aware of the recurring optical cable problems with  
22 Pantheris while it was in the R&D phase, and prior to the IPO. As CW3 stated, CW3 acquired this  
23 knowledge through regular conversations with personnel at Avinger’s headquarters. Indeed, as CW3  
24 stated, in the context of CW3’s day-to-day work and throughout CW3’s tenure at Avinger “you would  
25 always hear about imaging issues,” and the problems with imaging of the device were significant.  
26 CW3 attributed the ongoing image quality issues to the fact that when utilized in the field, the  
27 Pantheris device was subject to rigorous handling by the operator and/or physician. CW3 also  
28 acknowledged that the testing of Pantheris at Avinger headquarters in the laboratory context may not



1 have adequately simulated the actual usage by physicians. Another recurring problem that CW3  
 2 identified through reviewing multiple complaints over time was that balloons within the device often  
 3 did not properly inflate, if at all.

4 **C. Post-IPO Disclosures**

5 47. On July 12, 2016, Avinger issued a press release that pre-announced disappointing  
 6 preliminary second quarter 2016 results. The Company attributed its results, in part, to “lower than  
 7 expected” utilization of Pantheris in the second quarter. As a result, the Company lowered its full year  
 8 revenue guidance from a range of \$25 million to \$30 million to a range of \$19 million to \$23 million.  
 9 As the Company’s July 12 press release further stated:

10 Dr. John B. Simpson, Avinger’s Founder and Executive Chairman, stated, “Based on  
 11 our early commercial experience, we have continued to make improvements to  
 12 Pantheris, and in particular the robustness of its optical imaging fiber, and have  
 13 received positive feedback from physicians on the performance of the current device.

14 \* \* \*

15 The company now expects 2016 revenue to be in the range of \$19 million to \$23  
 16 million, representing year-over-year growth ranging from 78% to 115%, compared to  
 17 previous guidance for revenue in the range of \$25 million to \$30 million.

18 48. After the close of the market on July 12, 2016, the Company held an earnings call to  
 19 discuss its preliminary results for the second quarter of 2016. On that call, Defendant Soinski stated,  
 20 in part, as follows:

21 We remain encouraged by the continued growth of our installed base to 126 accounts  
 22 an increase of 19 accounts during the second quarter which is the second largest  
 23 quarterly increase we’ve achieved in our history.

24 However, utilization of disposables has been lower than we had expected. We  
 25 believe we’ve identified three main reasons that initial Pantheris utilization has been  
 26 slower than anticipated and we’re taking a series of actions to improve our  
 27 performance. First, we’re still helping physicians understand how Pantheris can best  
 28 fit into their PAD treatment paradigm both near-term in their current treatment  
 algorithms and longer term as they gain familiarity and use Pantheris in increasingly  
 complex cases.

\* \* \*

Second, we experienced some issues with device robustness as we mentioned on our  
 last earnings call and in our Form 10-Q filed on May 9, 2016. We’ve made changes  
 to the catheter and now believe that the most significant of these issues are behind us.

\* \* \*

1 The third item we've identified is a slower than anticipated ramp in sales force  
2 productivity.

3 \* \* \*

4 While sales this quarter didn't hit our internal expectations, we believe we've  
5 identified the root causes of the slower ramp and that our long-term opportunity  
6 remains exciting.

7 In addition, Defendant Simpson commented:

8 This quarter has been a valuable one for us as we've now observed Pantheris usage  
9 in a large number of operators in a wide range of lesions. We've also gained  
10 important physician feedback which we have used to implement some changes in the  
11 product and our sales' force's position in Pantheris. As I mentioned on the last call,  
12 while we have had some outstanding early-case experience [unintelligible] has been  
13 really remarkable. We have had some initial issues with device robustness, primarily  
14 imaging fiber robustness, which are not unusual for a groundbreaking new  
15 technology, certainly provided some challenges for our sales team.

16 I'm pleased to report that based on improvements we made to this device, and in  
17 particular to the robustness of the optical imaging fiber, physicians are relaying  
18 positive feedback on the improved product. And we now feel the Pantheris  
19 performance levels are within the normal range for a new and relatively complex  
20 product in our space.

21 Later in the call, Defendant Soinski referenced Defendant Simpson's earlier comments, when he noted  
22 that "as Dr. Simpson talked about, [we] have made some improvements to our number one product  
23 issue that we had early in the [Pantheris] launch."

24 49. In response to a later analyst question on the call regarding "device robustness issues"  
25 and issues with the imaging, and whether such issues were "fully behind you now," Defendant  
26 Simpson further stated as follows:

27 [S]o as it relates to the imaging fiber we have [unintelligible] almost like we put a  
28 strain relief and with the fiber. Because in very robust settings if you pull too hard  
over to cut or to open it, the fiber could crack and when the fiber crack[s] the images  
would degrade. So that was – it was never, ever even once a safety issue but it was a  
huge pain issue and you had to exchange devices and was kind of an annoyance.

I don't think we have to retrain around that because you lose the image so you have  
to exchange devices to put it into the device. And then the new strain relief seems to  
have eliminated that almost entire great majority of it. These fibers are fragile,  
they're tiny, they have enormous benefit but they are fragile and they have to be kind  
of used. Historically they had to be used very careful. Now, with the new devices  
you can be much less careful with them and they can still maintain their images and  
that's really the key element.

So, the fiber not only has it been say protected a little bit but also physicians are a  
little bit more cautious about how to use it. I don't think this had really affected the  
learning curve so much as it's been a little bit annoying. I don't know that it's

1 actually affected the ramp. If somebody has a fiber failure, they just put in a new  
2 device and they keep going. So I don't know if that answer[s] your question or not.

3 50. Thereafter, Defendant Simpson engaged in a further colloquy with another analyst  
4 regarding robustness issues and whether there were other product quality or design issues that had  
5 adversely impacted Pantheris:

6 **Analyst question:** *I just wanted to start with the robustness issues that you  
7 called out. Were there any other issues outside of the fiber  
8 optic cable crack issues if you will?*

9 **Defendant Simpson:**

10 *Yes. So I would say not a real genuine substance. The [unintelligible] were also  
11 fragile I would say and occasionally we have some balloon leaks and again nothing  
12 of safety concerns. But I think [unintelligible] that most annoying in which I think  
13 also the physicians that were using the device felt annoying is that you got all the  
14 trouble to get the device all set up on the console and everything done. You put the  
15 device in and you get down to the narrow end and then, you'll lose the light, and  
16 there was – and so, we have to really, really [unintelligible] fix that over the last, I'd  
17 say, six weeks, I don't remember seeing a catheter have that – physicians have that  
18 experience with the device with the new generation. So, the balloons . . . leaking . . .  
19 get some more CO2, that's not really – that doesn't seem to be as big of an issue.  
20 And all of these are getting better. The balloons we're making the – the balloons are  
21 stronger, and the fibers are more protected. So, I think everything is headed in the  
22 right direction.*

23 \* \* \*

24 **Analyst question:** *Okay. And the robustness issues seem to be relatively in the  
25 rear-view mirror. Is that right [for me to] think about it as  
26 it's going forward that these technical issues have been  
27 solved?*

28 **Defendant Simpson:**

I would say that that's – for [unintelligible] with 100%, but that's – 95%, those  
things are behind us. We're seeing – it's almost – I mean really, really rare compared  
to – I mean doc[tor]s will sometimes, you'd be surprised how aggressive the  
doc[tor]s will be forcing, pushing, jerking, twisting everything. And it's – and even  
though there's to be train[ing] against it, it still happen[s]. So I believe, though, that  
the robustness challenges that we found when we – in the initial launch, I think those  
are behind us.

51. Analysts were shocked by these disclosures. For example, a July 12, 2016 research  
report by BTIG stated the following:

After the close, AVGR released preliminary Q2 top-line results of \$4.7M, below the  
Street estimate of \$5.7M. In addition, mgmt lowered full year guidance by ~25% at  
the midpoint. The revenue miss alone is not horrendous early in launch, *but we  
found [management's] commentary alarming and plan to have near-term  
discussions with physician users.*

***Mgmt discussed product failures, and we see these as a meaningful problem. On the call, mgmt described issues with the catheter, including the light going out when reaching the narrowing of the artery and fiber issues. We had been under the impression these were entirely resolved months ago, but it seems while the company has made significant progress, issues still are more common than more-established competitive platforms. Some device failure early on is expected, but repeated issues (especially of the imaging component) could really slow adoption. We plan calls with docs to see how often they are having issues now that it seems they are not entirely resolved.***

[Emphasis added.]

52. On July 13, 2016, *Avinger's stock price fell \$4.54 per share, or a staggering 39.7%*, from \$11.43 at the close on July 12 to only \$6.89 at the close on July 13 on unusually heavy trading volume.

53. On August 1, 2016, Avinger issued a press release announcing its final financial results for the second quarter of 2016. Referencing the Company's product quality issues with Pantheris, the press release quoted Defendant Soinski as stating "[w]e have improved the Pantheris imaging fiber connection to enhance device robustness" as part of an effort to "driv[e] Pantheris utilization and revenue growth in the second half of the year." The Company also announced that total revenue for the quarter (\$4.7 million) was up sequentially only 3% compared to the immediately preceding quarter, even though the second quarter represented the first full quarter since the FDA had granted Pantheris 510(k) clearance on March 1, 2016. The Company further announced that its losses from operations for the second quarter of 2016 had risen to \$12.3 million (from \$9.1 million for the second quarter of 2015) and that the value of its cash and cash equivalents on hand had declined from \$43.1 million, as of December 31, 2015, to only \$22.4 million, as of June 30, 2016.

54. On August 5, 2016, the Company issued its report for the second quarter of 2016 on SEC Form 10-Q, which stated as follows:

***[W]e have in the past, and may in the future, become aware of performance issues with our products. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. We have addressed certain of these concerns and plan to make additional product changes and improvements as a result of this feedback. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised. Even if these issues are resolved and physician concerns addressed, future product performance issues may occur and our***

1 *reputation could suffer, which could lead to decreased sales of our products.* In the  
 2 second quarter of 2016, our revenue was adversely impacted by these product  
 3 performance issues. *We also had to incur additional expenses to make product*  
 4 *changes and improvements, including improvements to the Pantheris imaging*  
 5 *fiber connection, and to replace products in accordance with our warranty policy.*  
 6 *This additional expense, and any future expense that we may incur as a result of*  
 7 *future product performance issues, will negatively impact our financial*  
 8 *performance and results of operations.* If we are unable to improve the performance  
 9 of our products to meet the concerns of the physicians our revenue may decline  
 10 further or fail to increase.

11 [Emphasis added.]

12 55. Between the close of the market on July 29, 2016 (the last trading day before August 1)  
 13 and the close of the market on August 5, 2016, the price of Avinger common stock fell \$0.35 further,  
 14 or more than 7%, from \$4.94 to \$4.59 per share.

15 56. On August 16, 2016, in order to raise desperately needed funds in light of the  
 16 disappointing Pantheris launch (which was in turn the result of Pantheris' significant product quality  
 17 and/or design problems), the Company announced that it had completed a secondary public offering of  
 18 roughly 9.8 million shares. This secondary offering raised roughly an additional \$31.7 million to keep  
 19 Avinger afloat – but did so based on a secondary offering price of only \$3.50 per share.

20 57. On the morning of January 6, 2017, Avinger issued a press release that pre-announced  
 21 disappointing preliminary fourth quarter 2016 results. The Company announced that total revenue for  
 22 the fourth quarter of 2016 was expected to be only \$4.7 million, a decline of 11% sequentially from  
 23 the third quarter of 2016 (and that revenue from “disposable devices,” which included the Pantheris,  
 24 was expected to decline 5% over the same period to only \$3.7 million). The Company, while noting  
 25 that its disposable revenue “continues to ramp more slowly than anticipated,” tried to deflect attention  
 26 from continuing problems with the existing Pantheris product by emphasizing that the Company was  
 27 continuing to work on “improvements to our current version of Pantheris, which we plan to roll out in  
 28 the coming months.” The press release also noted that (even after taking into account the additional  
 \$31.7 million it had raised in its August 2016 secondary offering) the Company's cash and cash  
 equivalents position, as of December 31, 2016, was down to \$36.1 million and that its cash  
 expenditures for the fourth quarter of 2016 totaled \$11.0 million.

58. On January 6, 2017, Avinger's stock price fell \$0.60 per share, or more than 15%, from \$3.90 at the close on January 5 to close at only \$3.30 on January 6.

59. On March 6, 2017, Avinger announced its fourth quarter and full year results for 2016. Among other things, the Company announced that its total revenue for the fourth quarter of 2016 had decreased 12% from the immediately preceding quarter and confirmed that its revenue from disposable devices for the quarter had been only \$3.7 million (a 5% decline from the prior quarter). The Company also announced that its gross margin for the fourth quarter of 2016 had fallen to only 21% (down from 37% in the comparable quarter of 2015 and down sequentially from 30% in the third quarter of 2015) and that gross margins for the full year (2016) had fallen to only 15%, compared to 40% for 2015. The Company also confirmed that its loss from operations for the fourth quarter of 2016 was \$12.0 million (down only \$300,000 from the fourth quarter of 2015) and that its cash and cash equivalents position, as of December 31, 2016, was \$36.1 million.

60. After the close of the market, Avinger also held a conference call to discuss its fourth quarter and full year results for 2016. During the call, Avinger representatives discussed how product defect problems with Pantheris remained and had still not been satisfactorily resolved – and effectively admitted that the Company's prior Pantheris testing regimen had been inadequate and would need to be substantially toughened to avoid the kinds of product quality and design problems that had plagued the initial launch of the Pantheris. For example, as Defendant Soinski stated:

I would like to provide an update on our Pantheris product development efforts as we progress the next generation Pantheris . . . towards market launch. ***Our R&D and manufacturing teams have been working diligently to rollout a series of incremental improvements to our current version of Pantheris to improve the consistency and reliability of our currently marketed products*** while we are completing our verification and validation activities to ready the next generation of Pantheris for 510(k) submission midyear.

Recall that the new Pantheris device is a true upgrade, which brings a host of additional improvements and important new features and benefits to the Pantheris franchise, including [a] more [] robust shaft for better pushability and improved handle designs, a redesigned single balloon system for apposition and occlusion as well as an improved nosecone and longer nosecone option.

\* \* \*

We believe that the multiple improvements in this next generation device will allow us to broaden the applicable procedure market especially in tough to treat lesions and



1 that it will have a direct and an positive impact on increasing utilization rates in  
2 existing and new accounts.

3 In discussing Avinger's collapsing gross margins, Defendant Ferguson attributed much of the decline  
4 to the growth of the Company's manufacturing infrastructure associated with the commercial launch  
5 of Pantheris, but Defendant Ferguson also admitted that "[g]ross margin for the fourth quarter was also  
6 negatively impacted by *higher costs related to product warranties and excess and obsolete*  
7 *inventories*" – and that staggering decline in gross margins for the full year (2016) to only 15% was  
8 also "primarily attributable to the growth in manufacturing infrastructure in conjunction with the  
9 launch of Pantheris *and higher costs related to product warranties and excess and obsolete*  
10 *inventories.*" [Emphasis added.]

11 61. Later on the same call, in discussing Avinger's plans to try to reverse its calamitous  
12 performance by launch certain "next generation" Pantheris products, Defendant Soinski also  
13 referenced the need for Avinger to toughen its prior testing standards to avoid a repeat of its disastrous  
14 launch of the its existing Pantheris product:

15 As we look at [getting FDA approval for the next Pantheris] device, . . . we're giving  
16 ourselves [a] little time there, because *one of things that we've done, as I think*  
17 *we've talked about in past calls, is we've made our verification and validation,*  
18 *testing and protocol suffer a little more comprehensive because we want to make*  
19 *sure we're avoiding any potential quality issues prior to launch.* So, we want to  
20 take the time to make sure that we've [got] these products right. We're very, very  
21 happy with the development programs that we're moving forward [with]. We've  
22 also pulled certain of the improvements that will be . . . in the next generation of  
23 Pantheris into our current device.

24 So, we'll be rolling out this quarter and next quarter certain improvements related to  
25 the inflation system, related to the nosecone on our current device.

26 [Emphasis added.]

27 In addition, in response to an analyst question about the Company's declining margins and rising costs  
28 for product warranties, Defendant Ferguson stated:

29 *Yes. So, in terms of gross margins, we've talked quite a bit about some of the*  
30 *reliability issues with Pantheris since it launched, and that has translated to higher*  
31 *level of returns. And so that really is the main driver of higher than planned*  
32 *warranty expense.* We think we've gotten that under control pretty well *but we*  
33 *would expect to continue to have it be higher than we really want it to be for the*  
34 *next couple of quarters until we can get some of these improvements in place.* And  
35 those will be both, some of the incremental improvements that will be coming out  
36 sooner and then the next generation of Pantheris, which is more of a wholesale  
37 upgrade[] of the device later in the year. So that's the main driver[.]



62. On March 7, 2017, *Avinger's stock price fell a further \$0.53 per share, or 20%*, from \$2.65 at the close on March 6 to only \$2.10 at the close on March 7, 2017.

63. On April 10, 2017, Avinger announced poor preliminary first quarter of 2017 results, including total revenue of approximately \$3.5 million, a decrease of 22% from the first quarter of 2016 and a sequentially decline of 25% from the immediately preceding fourth quarter of 2016, and revenue from disposable devices for the first quarter of 2017 of only \$2.9 million, a 12% decrease compared to the first quarter of 2016 and down sequentially 22% from the immediately preceding quarter. The Company also announced that it had been conducting a review of potential strategic alternatives, including raising capital from strategic investors, partnerships for distribution of products outside the United States, and a sale or merger of the Company. The Company was once again also forced to admit that it had continued to experience significant challenges with Pantheris' product reliability and related efforts to commercialize the Company's lumivascular technology and that as a result, the Company would be making "adjustments" to its business" by, among other things, slashing its workforce by approximately 33%. In particular, the Company's April 10, 2017 press release stated:

The Company . . . announced that it has been conducting a review of various strategic alternatives focused on maximizing shareholder value. Potential strategic alternatives being explored and evaluated as part of this review include, but are not limited to, raising capital from strategic investors, partnerships for distribution of products outside the U.S., and a sale or merger of the Company.

"Avinger has achieved a great deal in the last year by bringing Pantheris OCT-guided atherectomy to market, increasing our installed base of Lumivascular accounts and presenting compelling two-year data from our VISION study. *However, we have also encountered challenges with product reliability and the broad commercialization of our Lumivascular technology.* Consequently, we have decided to make adjustments in our business as we prepare for the launch of our next generation Pantheris and Below-the-Knee products in late 2017 and early 2018," said Jeff Soinski, Avinger's president and CEO.

\* \* \*

### **Organizational Realignment**

The Company is reducing its workforce by approximately 33% compared to year-end 2016, to a total of 131 full-time equivalent employees, under a plan expected to be substantially completed this week. The plan is designed to focus the Company's commercial efforts on driving catheter utilization in its strongest markets, around its most productive sales professionals. The Company's field sales personnel will be reduced to 32 down from 60 people as of December 31, 2016.

1 [Emphasis added and in original.]

2 64. Analysts again were shocked. For example, as an April 11, 2017 Stephens analyst  
3 report stated:

4 **A Disappointing Pre-Announcement.** Following the market's close on Monday,  
5 April 10, AVGR pre-announced 1Q17 revenue of \$3.5 million, approximately \$1.3  
6 million below our former \$0.1 million below consensus quarterly revenue estimate of  
7 \$4.8 million. Specifically, AVGR expects 1Q17 disposable device revenue of \$2.9  
8 million (Stephens former estimate of \$3.8 million), implying a (12.0%) annual  
9 decline. Additionally, the Company sold a total of 5 Lightbox units (Stephens former  
estimate of 15 units) during the quarter, bringing the installed base to 161 accounts.  
As a result, capital revenue declined 50.0% year-over-year to \$0.6 million (Stephens  
former estimate of \$1.0 million). AVGR exited the 1Q17 operating period with \$23.0  
million in cash and cash equivalents, implying a cash burn of \$13.1 million during  
the quarter.

10 65. On April 11, 2017, Avinger's stock price fell a further \$1.00 per share, *or an*  
11 *astounding 62.5%*, from \$1.60 per share at the close on April 10 to close at only \$0.60 per share on  
12 April 11 on unusually heavy trading volume.

13 66. On May 4, 2017, the Company announced its results for the first quarter of 2017,  
14 including total revenue of only \$3.5 million – a 23% decline from the first quarter of 2016 and a 25%  
15 decline from the fourth quarter of 2016.

16 67. After the close of the market later that day, Avinger conducted a conference call with  
17 analysts. During that call, Defendant Soinski stated:

18 As we've described before, the [latest] Pantheris . . . device [that we hope to launch  
19 in coming quarters] is a true upgrade, which brings a host of additional  
20 improvements and important new features and benefits to the Pantheris franchise,  
21 including a more robust shaft, an improved handle design, a redesigned single  
balloon system for both apposition and occlusion as well as an improved nose cone  
and longer nose cone option.

22 *We believe that the multiple improvements in this next generation device will*  
23 *significantly improve device reliability* and usability and will result [in] an increased  
utilization compared to current levels.

24 68. On May 5, 2017, the price of Avinger common stock closed at \$0.49, down another  
25 16% from its prior closing price of \$0.59 on May 4.

26 69. In the following weeks and months, the price of Avinger's common stock has only  
27 continued to fall. On November 21, 2017 (the date of this filing), Avinger shares closed at \$0.23 per  
28

1 share – reflecting a staggering decline of \$12.77 per share, *and more than a 98% decline*, from its  
 2 IPO price of \$13.00 per share.

### 3 CLASS ACTION ALLEGATIONS

4 70. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of  
 5 Civil Procedure on behalf of a Class, consisting of all persons and entities that purchased or otherwise  
 6 acquired shares of Avinger common stock pursuant and/or traceable to the IPO Registration Statement  
 7 issued in connection with the Company's IPO and who were damaged thereby (the "Class").  
 8 Excluded from the Class are each of the Defendants, their respective successors, assigns, parents, and  
 9 subsidiaries, the past and current executive officers and directors of Avinger and the Underwriter  
 10 Defendants, the legal representatives, heirs, successors or assigns of the Individual Defendants, and  
 11 any entity in which any of the foregoing excluded persons have or had a majority ownership interest.

12 71. The members of the Class are so numerous that joinder of all members is impracticable.  
 13 Avinger sold approximately five million shares in the IPO and thereafter Avinger's common stock was  
 14 actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs  
 15 at this time, and can only be ascertained through appropriate discovery, Plaintiffs believe that there are  
 16 hundreds or thousands of members in the proposed Class. Moreover, record owners and other  
 17 members of the Class may be identified from records maintained by Avinger or its transfer agent and  
 18 may be notified of the pendency of this action by mail using forms of notice similar to that customarily  
 19 used in securities class actions.

20 72. Plaintiffs' claims are typical of the claims of the members of the Class, as all members  
 21 of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law as  
 22 alleged herein.

23 73. Plaintiffs will fairly and adequately protect the interests of the members of the Class  
 24 and have retained counsel competent and experienced in class and securities litigation.

25 74. Common questions of law and fact exist as to all members of the Class and predominate  
 26 over any questions solely affecting individual members of the Class. Among the questions of law and  
 27 fact common to the Class are:

28 (a) whether the Securities Act was violated by Defendants' acts as alleged herein;

(b) whether statements made, authorized, or disseminated by Defendants to the investing public in connection with the IPO, including the IPO Registration Statement, misrepresented and/or omitted material facts about Avinger's business, operations, or prospects; and

(c) the extent to which the members of the Class have sustained damages and the proper measure of damages.

75. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

**FIRST CLAIM**  
**Violation of §11 of the Securities Act**  
**(Against All Defendants)**

76. Plaintiffs repeat and reallege each and every allegation contained above, except any allegation of fraud, recklessness, or intentional misconduct. Plaintiffs specifically disclaim any allegations that are based upon fraud, recklessness, or intentional misconduct.

77. This Count is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all Defendants.

78. The IPO Registration Statement was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and otherwise omitted to state material facts required to be stated therein.

79. Avinger was the issuer and registrant for the IPO. The Defendants named herein were responsible, either directly or as a matter of law, for the contents and dissemination of the IPO Registration Statement.

80. As issuer of the shares, Avinger is strictly liable to Plaintiffs and the Class for the misstatements and omissions.

81. In addition, all Defendants, other than Avinger, are also strictly liable to Plaintiffs and the Class for the misstatements and omissions. None of the Defendants named herein made a

1 reasonable investigation or possessed reasonable grounds for the belief that the statements contained  
2 in the IPO Registration Statement were true and without omissions of any material facts and were not  
3 misleading.

4 82. By reason of the inaccuracies and omissions contained in the Registration Statement  
5 and their role in its preparation, dissemination and/or signing, and/or the other misconduct alleged  
6 herein, each Defendant violated and/or controlled a person who violated §11 of the Securities Act.

7 83. Plaintiffs acquired Avinger shares pursuant and/or traceable to the IPO Registration  
8 Statement.

9 84. Plaintiffs and the Class have sustained damages under §11(e) of the Securities Act, as  
10 the value of the shares of Avinger common stock declined following the IPO.

11 **SECOND CLAIM**  
12 **Violation of §15 of the Securities Act**  
**(Against the Individual Defendants)**

13 85. Plaintiffs repeat and reallege each and every allegation contained above, except any  
14 allegation of fraud, recklessness, or intentional misconduct. Plaintiffs specifically disclaim any  
15 allegations that are based upon fraud, recklessness, or intentional misconduct.

16 86. This count is asserted against the Individual Defendants and is based upon §15 of the  
17 Securities Act.

18 87. The Individual Defendants, by virtue of their offices, directorship, and specific acts  
19 were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Avinger  
20 within the meaning of §15 of the Securities Act. The Individual Defendants had the power and  
21 influence, and exercised the same, to cause Avinger to engage in the acts described herein.

22 88. The Individual Defendants' positions made them privy to and provided them with  
23 actual knowledge of the material facts concealed from Plaintiffs and the Class.

24 89. By virtue of the conduct alleged herein, the Individual Defendants are liable to  
25 Plaintiffs and the Class for damages they have suffered.

26 WHEREFORE, Plaintiffs pray for relief and judgment as follows:

27 (A) Determining that this action is a proper class action pursuant to Fed. R. Civ. P. 23;  
28

(B) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages suffered in connection with their purchases of Avinger common stock pursuant or traceable to the defective IPO Registration Statement to the maximum extent permitted under § 11(e) of the Securities Act, and any other applicable law, in an amount to be proven at trial, plus interest thereon;

(C) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(D) Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiffs hereby demand a trial by jury.

Dated: November 21, 2017

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*Additional Counsel for Plaintiffs*



**CERTIFICATE OF SERVICE**

I hereby certify that on November 21, 2017, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List, and I hereby certify that I caused the foregoing document or paper to be mailed via the United States Postal Service to the non-CM/ECF participants indicated on the Manual Notice List.

s/ John T. Jasnoch  
John T. Jasnoch